

AMENDMENTS TO THE CLAIMS

1. (Currently amended) A ~~program—storage~~ computer readable media comprising computer-executable instructions for continuously analyzing trial data of an ongoing blinded clinical trial, said computer-executable instructions being for:

accessing a trial database comprising trial data of subjects in an ongoing blinded clinical trial comprising a multi-arm study without compromising integrity of the ongoing blinded clinical trial;

accessing a blinding database comprising subject identifiers and associated study group identifiers without compromising the integrity of the ongoing blinded clinical trial, wherein a subject's study group being identifiable by a study group identifier;

generating a grouped database from the trial database and the blinding database for statistical analysis without compromising the integrity of the ongoing blinded clinical trial, the grouped database grouping the trial data of the subjects based on their study group;

performing a statistical analysis on the accessed trial database without suspending and compromising the integrity of the ongoing blinded clinical trial;

determining whether the result of the statistical analysis exceeds a predetermined threshold value;

storing the result of the statistical analysis in a memory device; and
repeating said computer-executable instructions for accessing a trial database, performing and determining while the blinded clinical trial is ongoing without compromising the integrity of the ongoing blinded clinical trial if it is determined that the result of the statistical analysis does not exceed the predetermined threshold value, then repeating said computer-executable

~~instructions for accessing a trial database, performing and determining while the blinded clinical trial is ongoing.~~

2. (Currently amended) The ~~program-storage~~ computer readable media of claim 1, prior to performing a statistical analysis, further comprising computer-executable instructions for:
 - reading a user defined criteria that defines the level of cleanliness of the trial data for statistical analysis; and
 - retrieving only those trial data that meet the user defined criteria from the trial database.
3. (Currently amended) The ~~program-storage~~ computer readable media of claim 1, further comprising ~~the~~ computer-executable instruction for waiting for a predetermined time period prior to the repeating said computer-executable instruction for accessing a trial database, performing and determining while the blinded clinical trial is ongoing if it is determined that the result of the statistical analysis does not exceed the predetermined threshold value.
4. (Canceled)
5. (Currently amended) The ~~program-storage~~ computer readable media of claim 1, further comprising computer-executable instruction for storing the grouped database in a memory device that is inaccessible by any user.
6. (Currently amended) The ~~program-storage~~ computer readable media of claim 1, wherein said computer-executable instruction for performing a statistical analysis without locking the trial database.
7. (Currently amended) The ~~program-storage~~ computer readable media of claim 1, further comprising computer-executable instructions for:

reading a predefined criteria that defines the level of cleanliness of trial data required for analysis; and

retrieving only those trial data that meet the predefined criteria from the trial database.

8. (Currently amended) The ~~program—storage~~ computer readable media of claim 7, further comprising computer-executable instruction for storing the grouped database in a memory device that is inaccessible by any user to preserve the blindness of the ongoing blinded clinical trial.
9. (Currently amended) The ~~program—storage~~ computer readable media of claim 1, further comprising -computer-executable instruction for alerting a user if it is determined that the result of the statistical analysis exceeds the predetermined threshold value.
10. (Currently amended) The ~~program—storage~~ computer readable media of claim 9, wherein the predetermined threshold value includes a predetermined statistical significance value.
11. (Currently amended) The ~~program—storage~~ computer readable media of claim 10, wherein said computer-executable instruction for performing a statistical analysis comprises computer-executable instructions for:
 - retrieving a user defined statistical model; and
 - running the retrieved user defined statistical model on the trial database.
12. (Currently amended) A ~~program—storage~~ computer readable media comprising computer-executable instructions for continuously analyzing trial data of an ongoing blinded clinical trial, said computer-executable instructions being for:

accessing a trial database comprising blinded trial data of subjects in an ongoing blinded clinical trial comprising a multi-arm study without compromising integrity of the ongoing blinded clinical trial;

accessing a blinding database containing subject identifiers and associated study group identifiers without compromising the integrity of the ongoing blinded clinical trial, each study group identifier identifying to which study group an associated subject belongs;

producing a grouped database from the trial database and the blinding database without compromising the integrity of the ongoing blinded clinical trial, the grouped database grouping the trial data according to the study group;

performing a statistical analysis on the produced grouped database without suspending and compromising the integrity of the ongoing blinded clinical trial;

determining whether the result of the statistical analysis exceeds a predetermined threshold value;

storing the result of the statistical analysis in a memory device; and

repeating said computer-executable instructions for accessing a trial database, producing a grouped database, performing a statistical analysis, and determining while the blinded clinical trial is ongoing without compromising the integrity of the ongoing blinded clinical trial if it is determined that the result of the statistical analysis does not exceed the predetermined threshold value, ~~then repeating said computer-executable instructions for accessing a trial database, producing a grouped database, performing a statistical analysis, and determining while the blinded clinical trial is ongoing.~~

13. (Currently amended) The ~~program storage~~ computer readable media of claim 12, prior to performing a statistical analysis, further comprising computer-executable instructions for:

reading a user defined criteria that defines the level of cleanliness of trial data for statistical analysis; and

retrieving only those trial data that meet the user defined criteria from the trial database for statistical analysis.

14. (Currently amended) The ~~program-storage~~ computer readable media of claim 12, further comprising computer-executable instruction for storing the produced grouped database in a memory device that is inaccessible by any user.
15. (Currently amended) The ~~program-storage~~ computer readable media of claim 12, wherein said computer-executable instruction for performing a statistical analysis without locking the trial database.
16. (Currently amended) The ~~program-storage~~ computer readable media of claim 12, further comprising computer-executable instruction for alerting a user if it is determined that the result of the statistical analysis exceeds the predetermined threshold value.
17. (Currently amended) The ~~program-storage~~ computer readable media of claim 16, wherein the predetermined threshold value includes a predetermined statistical significance value.
18. (Currently amended) A system for continuously analyzing an ongoing blinded clinical trial comprising:
 - a storage device operable to store a trial database comprising trial data of subjects in an ongoing blinded clinical trial comprising a multi-arm study;
 - a processor coupled to the storage device; and
 - an analysis program executable by the processor and operable to:
 - access the trial database to retrieve the trial data without compromising integrity of the ongoing blinded clinical trial;
 - access a blinding database comprising subject identifiers and associated study group identifiers without compromising the integrity of the

ongoing blinded clinical trial, wherein a subject's study group being identifiable by a study group identifier;

generate a grouped database from the trial database and the blinding database for statistical analysis without compromising the integrity of the ongoing blinded clinical trial, the grouped database grouping the trial data of the subjects based on their study group;

perform a statistical analysis on the trial database without suspending and compromising the integrity of the ongoing blinded clinical trial;

determine whether the output result of the statistical analysis exceeds a predetermined threshold value; and

repeat the statistical analysis while the blinded clinical trial is ongoing without compromising the integrity of the ongoing blinded clinical trial if it is determined that the result of the statistical analysis does not exceed the predetermined threshold value.

19. (Original) The system according to claim 18, wherein the analysis program is further operable to:

read a user defined criteria that defines the level of cleanliness of trial data for statistical analysis; and

retrieve only those trial data that meet the user defined criteria from the trial database.

20. (Original) The system according to claim 18, wherein if the analysis program determines that the result of the statistical analysis does not exceed the predetermined threshold value, then the analysis program waits for a predetermined time period prior to repeating the statistical analysis.

21. (Canceled)

22. (Previously presented) The system according to claim 18, further comprising a memory device coupled to the processor and being inaccessible to any user, wherein the grouped database is stored only in the memory device.
23. (Original) The system according to claim 18, wherein the analysis program performs the statistical analysis without locking the trial database.
24. (Original) The system according to claim 18, wherein the analysis program is further operable to alert a user if it determines that the result of the statistical analysis exceeds the predetermined threshold value.